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10/594,349	05/29/2007	Masato Miyake	690121.410USPC	5580

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EXAMINER

EPPS -SMITH, JANET L

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1633

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02/23/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. Claims 1-2, 5-41 are presently pending.
2. Claims 13-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 112

4. The rejection of claims 3-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment.

Claim Rejections - 35 USC § 103

5. Claims 1-2, 5-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hanenberg et al. or Rabbani et al. in view of Skorstengaard et al. and Kitazato et al.
6. Applicant's arguments filed 02/07/2011 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that neither the cited references, nor the prior art suggest an actin acting substance comprising at least amino acids 21 to 241 of SEQ ID NO: 11, constituting an Fnl domain, or a variant thereof for increasing the efficiency of introducing a target substance into a cell with any reasonable expectation of success. Furthermore, Applicants argue (1) that Hanenberg et al. fails to suggest an actin acting substance comprising at least amino acids 21 to

Art Unit: 1633

241 of SEQ ID NO: 11 constituting an Fnl domain, or a variant thereof. In contrast, Hanenberg et al. disclose recombinant fibronectin fragments consisting of fibronectin type III domains, e.g., CH-271 and CH-296. (2) Rabbani et al. fail to suggest an actin acting substance comprising at least amino acids 21 to 241 of SEQ ID NO: 11 constituting an Fnl domain, or a variant thereof. (3) Skorstengaard et al. merely discloses the primary sequence of bovine fibronectin and domain structure of bovine fibronectin, but are completely silent with regard to an actin acting substance comprising at least amino acids 21 to 241 of SEQ ID NO: 11 constituting an Fnl domain that can be used for increasing the efficiency of introducing a target substance into a cell. (4) Kitazato et al. does not remedy the insufficiencies of Hanenberg et al., Rabbani et al., and Skorstengaard, and thus, all four references cited by the Examiner individually and collectively fail to establish a prima facie case of obviousness against the presently claimed invention.

7. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

8. Contrary to Applicant's assertions, Applicant's arguments do not take the place of evidence of non-obviousness. Absent evidence to the contrary, the prior art clearly teaches the use of fibronectin for increasing the efficiency of introducing a target substance into a cell. Although, the prior art does not specifically disclose the use of a

Art Unit: 1633

compound comprising at least amino acids 21 to 241 of SEQ ID NO: 11, contrary to Applicant's assertions the fibronectin disclosed in Hanenberg et al. and Rabbani et al. encompass the use of fibronectin, wherein the fibronectin is a variant of a fibronectin comprising at least amino acids 21 to 241 of SEQ ID NO: 11.

9. As stated in the prior Office Action, absent evidence to the contrary the skilled artisan would have been motivated to use a polypeptide comprising the Fn1 domain, particularly fibronectin in a manner to increase gene transduction into a cell as evidenced by the teachings of Hanenberg et al., which discloses the use of compositions comprising fibronectin to increase the efficiency of retroviral gene transfer. Furthermore, Rabbani et al. also provides guidance to the use of fibronectin as a gene delivery substance.

10. Additionally, in regards to substituting the fibronectin sequence of Skorstengaard et al. for the fibronectin disclosed in Hanenberg et al. or Rabbani et al., the ordinary skilled artisan would have been motivated to make this modification because as per MPEP § 2144.06 [R-6], it is *prima facie* obvious to substitute art recognized equivalents for the same purpose. Applicant's arguments do not take the place of evidence of nonobviousness.

11. Secondly it would have been obvious to the ordinary skilled artisan to modify the gene delivery particles described in the primary references with the gold colloid modification of Kitazato et al. since the prior art teaches that this class of modification is well suited for gene delivery vehicles and is useful for visualization of the modified particles.

Art Unit: 1633

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633